MARYLAND
HEALTH CARE
COMMISSION

ISSUE & POLICY BRIEF

Informed Consumers . . . Accountable Health Care

ORGAN TRANSPLANT SERVICES

The Maryland Health Care Commission (MHCC or the Commission) is an independent commission, members of which are appointed by the Governor with the advice and consent of the Maryland Senate. The responsibilities of the Commission include, among others, the implementation of a certificate of need (CON) program for certain health care facilities and services, and the adoption of a State health plan (SHP) for facilities and services regulated by the CON program. The Commission coordinates the performance of its regulatory responsibilities and duties with the Department of Health and Mental Hygiene, the Health Services Cost Review Commission, and other administrative agencies in the state. The Commission is authorized to appoint advisory committees to make recommendations to the Commission on organ transplant and other specialized health care services.

Regulation of Organ Transplant Services in Maryland
In Maryland, a provider is required by law to have a certificate of need issued by the Commission before developing or operating a new health care service for organ transplant surgery. Regulations adopted by the Commission describe how the law will be applied.

The Commission has established criteria that are used to evaluate all proposals subject to its review and approval. In order to establish a new service, under the CON program, the provider must:

- propose to meet an unmet need, based on the analysis in the State health plan or, in the absence of such an analysis, evidence of the unmet needs of the population as identified by the provider.
- develop a program that will be financially viable.
- show ongoing compliance with the terms of previously awarded CONs.

When reviewing a CON application, the Commission must consider:

- the availability of more cost-effective alternatives at other existing facilities or in competitive proposals.
- the impact of the proposal on existing providers in the service area, including geographic and demographic access to services, and the costs and charges of other providers.

In addition, there are numerous issues that are specific to the development and utilization of organ transplant services. To address those issues, the Commission has also adopted specific policies and standards to review the availability, accessibility, quality, and cost of organ transplant services in nonfederal hospitals in Maryland. MHCC may waive its policies for research proposals that meet its conditions. (Refer to State Health Plan COMAR 10.24.15 for details.)

Certificate of Need Coverage
CON approval is required for each transplant program involving major solid organs (kidney, liver, pancreas, heart and lung), intestine or small bowel, hematopoietic stem cells and other transplantable cells. A merged hospital system may not relocate any part of any existing organ transplant program to another hospital within its system without obtaining an additional CON.

Transplant Services Allocation System
The Commission does not regulate the distribution or allocation of organs. The United Network for Organ Sharing (UNOS) controls the distribution of solid organs at a national level, under contract with the Health Resources and Services Administration of the U.S. Department of Health and Human Services. The Commission regulates the number and distribution of centers that perform the transplants. Under the SHP chapter for this specialized service, MHCC has established two regional service areas based on those developed by UNOS. The Organ Procurement Organizations (OPOs) covering the two regions are the Transplant Resource Center of Maryland (TRC) and the Washington Regional Transplant Consortium (WRTC). TRC provides service to residents of Maryland, excluding Charles, Montgomery and Prince George's counties. WRTC serves those counties, Washington, D.C. and Northern Virginia.

Relationship between Volume and Outcomes
There is evidence that the volume of organ transplant procedures correlates with outcomes such as survival rates. Consequently, the Commission has established minimum volume requirements for each transplant program.

Glossary of Terms
Hematopoietic stem cells - Cells that give rise to distinct daughter cells, one a replica of the stem cell, one a cell that will further proliferate and differentiate into a mature blood cell.
Organ Procurement Organization (OPO) - An organization designated by the federal Centers for Medicare and Medicaid Services (CMS) and responsible for the procurement of organs for transplantation and the promotion of organ donation.
United Network for Organ Sharing (UNOS) - A nonprofit charitable organization that holds the contract from the U.S. Department of Health and Human Services to operate the Organ Procurement and Transplantation Network (OPTN). UNOS matches organ donors to waiting recipients. Through its policies, UNOS ensures that all patients have a fair chance at receiving the organ they need, regardless of age, sex, race, lifestyle, religion, or financial or social status.

MHCC promotes quality of care by requiring programs to perform a sufficient number of procedures to maintain skills and experience of medical, nursing and allied personnel. For providers gaining new CON approval effective after January 1999, the Commission may withdraw the CON, if they are found not to be in compliance with the conditions of approval. MHCC collects data to monitor program volumes.

As new classes of cell therapies and organ transplants are developed, the Commission will determine minimum volume requirements on a case-by-case basis, based on the best information available at the time of application.

Certification and Accreditation

The CON process provides a tool for examining quality issues before the provider begins operation of a new service. Unlike the Office of Health Care Quality (OHCQ) within the Department of Health and Mental Hygiene, or accrediting organizations, the CON process is not designed to monitor quality on an ongoing basis. The OHCQ, however, does not have licensure standards that are specific for organ transplant services.

The Commission does not duplicate standards related to quality that State licensing or national accrediting authorities already have adopted and enforced. Instead, the Commission requires each Maryland transplant program to comply with all appropriate requirements for certification and/or accreditation by UNOS and FAHCT, as applicable. The Commission requires accreditation to ensure quality of care provided by transplant centers is regularly reviewed and determined to meet specific standards.

The Maryland Commission on Kidney Disease also certifies dialysis and renal transplantation services for end-stage renal disease for the purpose of reimbursement (COMAR 10.30.01).

Cost

The Health Services Cost Review Commission (HSCRC) reviews and approves the reasonableness of the rates of hospitals in Maryland. It approves rates that will allow effective, efficient hospitals to remain solvent. In adopting standards regarding cost, efficiency, cost effectiveness, or financial feasibility, the Commission takes into account relevant methodologies of HSCRC.

Future Utilization

Regulating the supply and distribution of transplant centers is intended to facilitate equitable access to high quality care for everyone. Due to rapidly changing technologies, which may have an impact on increasing or decreasing the utilization of transplant services, the Commission will re-evaluate its projection of need for new transplant programs every three years. Future utilization is dependent on the demand for the service, as well as the supply of organs available. The need for transplantation is increasing as the criteria used in patient selection become less restrictive. As this demand is increasing, organ supply is also increasing with the advent of living donation. On the other hand, it is also believed that the need for some transplants will decrease as alternative treatments are developed for illnesses that lead to transplant procedures.

In addition, future level of need for services is dependent on changes in population and the migration of patients in and out of the regional service areas.

Current and possible future developments and their potential impact on demand and utilization

Increase	*Decrease*
Demand • Improved post-operative rejection management, expanding selection criteria for waiting list • Artificial liver – as a bridge to transplantation • LVAD - as a bridge to heart transplantation • Increased insurance coverage Utilization • Increase in cadaveric donor pool – older donors, non-heart beating, national donor card • Increase in living donation (kidney, liver, intestine) • Xenotransplants	• Increased health promotion and disease prevention, so that patients do not reach the point of end-stage organ failure, e.g., reduced incidence of diabetes or its complications • Advances in medical treatment for chronic diseases, e.g., anti-viral medications impacting on end-stage liver failure and angiotensin-converting enzyme (ACE) inhibitors on heart failure • Refinement of implantable mechanical heart

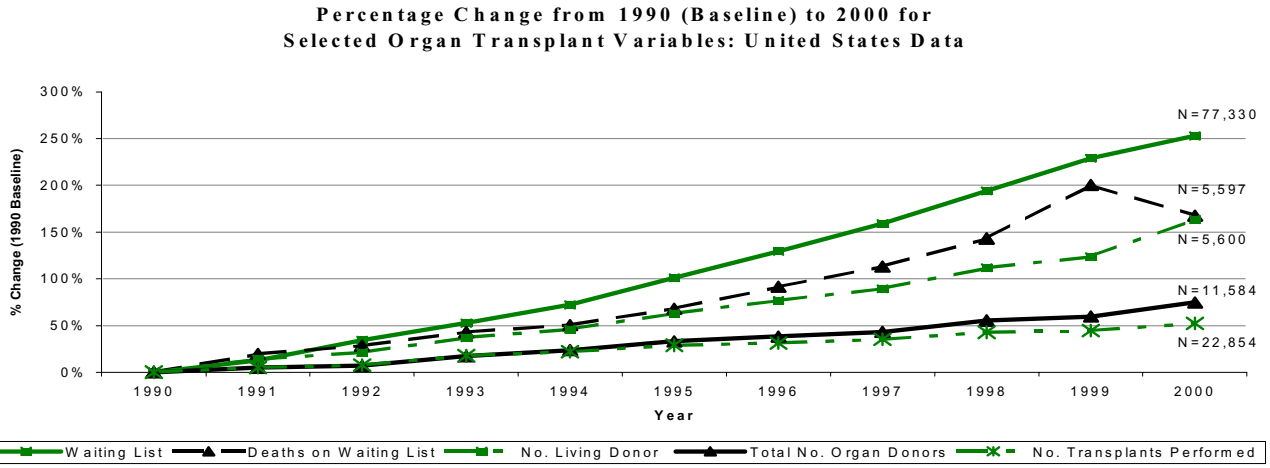
Highlights of National Trends in Organ Transplantation

The national waiting list for organ transplants continues to increase at a much greater rate than the supply of organs. From 1998 to June 2001, there was an 8 percent average yearly increase in the waiting list; however, during the period from 1998 to 2000, there was only a 3 percent average yearly increase in transplants occurring.

The demand for transplants continues to be limited by organ supply. The number of organ donors has been steadily increasing (2 percent per year from 1998 to 2000), however, not at a rate to keep pace with the waiting list. One reason for this increase is the impact in recent years of the greater use of living donors, which has increased at an average of 12 percent per year from 1998 to 2000.

This ever-widening gap between transplant demand and organ supply continues to have an impact on the number of deaths occurring while potential recipients are on the waiting list (5 percent average yearly increase from 1998 to 2000).

In 1999, 8 percent of all organ recipients and 3 percent of persons on the waiting list nationally were aged less than 18 years. Pediatric candidates experienced shorter waiting times, on average, than adults.



Source: UNOS Scientific Registry Data as of April 7, 2001. Waiting list on the last day of each year, except for year 2000 (waiting list on June 29, 2001 and annualized). Due to changes in reporting methods, deaths on the waiting list in 1998, 1999, and 2000 are not directly comparable and should not be compared to data prior to 1998. Data subject to change based on future data submission or correction.

Maryland and Washington Regional Trends in Organ Transplantation

Hospitals within the Maryland region currently performing solid organ transplants are Johns Hopkins Hospital and the University of Maryland Medical Center; Greater Baltimore Medical Center and Sinai Hospital, along with the above listed facilities, provide services for hematopoietic stem cell transplants. The Washington region includes Holy Cross Hospital in Maryland plus a number of hospitals within Washington, D.C. and Northern Virginia that provide transplant services to Maryland residents. The Maryland and Washington regional statistics include data from the Maryland, Washington, D.C. and Northern Virginia hospitals.

In the Maryland and Washington regions, kidney transplants led all solid organ transplant procedures with 816 surgeries in 2000. Kidney transplantation also had the greatest increase in utilization over the period of 1998 to 2000 (19 percent average yearly increase). Pancreas, liver and lung transplants also increased over the same time period. In contrast, combined kidney-pancreas and heart transplants decreased in 2000 compared to 1998.

Utilization at Maryland and Washington Regional Transplant Centers: 1998-2000

Organ	1998	1999	2000	Average Increase per Year (1998-2000)
Kidney	592	751	816	19%
Pancreas	44	78	55	13%
Kidney-Pancreas	57	33	36	-18%
Liver	124	133	136	5%
Heart	51	50	37	-14%
Lung	37	46	44	9%
Heart-Lung	0	1	2	-
Total MD/DC/ NVA	**905**	**1,092**	**1,126**	**12%**
Total National	**21,409**	**21,659**	**22,854**	**3%**

Source: UNOS Scientific Registry Data as of July, 2001. (MHCC Data Request)

The overall rate of solid organ transplantation in the Maryland and Washington regions increased faster than the national trend, 12 percent versus 3 percent average yearly increase from 1998 to 2000, reflecting geographic differences in such factors as the proportion of the population within the criteria set for donation and the rates of compliance with laws requiring referral to an OPO.

Glossary of Terms

Allocation rules - Rules or policies, generally based upon medical criteria, established by the OPTN to guide and regulate organ allocation or distribution in the United States.

Cadaveric donor - An individual whose tissues or organs are donated after death. Cadaveric donations are from two sources: patients who have suffered brain death, and patients whose hearts have irreversibly stopped beating. The latter group is referred to as "non-heart beating donors."

Donor - An individual (cadaveric or living) that supplies living tissue to be used in another person for transplantation.

End-stage organ failure – Irreversible damage to a vital organ, e.g., heart, lung, pancreas and intestine, resulting in deteriorating functioning resulting in failure.

Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) - An accreditation program that encompasses all phases of hematopoietic collection, processing and transplant.

Left Ventricular Assist Device (LVAD) - A mechanical pump implanted into a patient with heart failure that maintains blood circulation.

Living donor - Living person who donates organ(s) for transplantation, including a kidney, or a segment of the lung, liver, pancreas or intestine.

Organ procurement - The process of donor screening, and the evaluation, removal, preservation, and distribution of organs for transplantation.

Recipient - One who receives an organ, tissue, or cells.

Waiting list - After evaluation by a team of transplant professionals, a patient is added to the national waiting list by a transplant center. Lists are specific to both geographic area and organ type: heart, lung, kidney, liver, pancreas, intestine, heart-lung, and kidney-pancreas. Each time a donor organ becomes available, a computer generates a list of potential recipients based on factors that include genetic similarity, organ size, medical urgency, and time on the waiting list. Some patients may be listed at more than one center for the same organ type or for multiple organs. The practice of multiple listing appears to have declined over time, especially since the definition of "local transplant" was expanded to include all transplant centers within an OPO's service area.

Xenotransplantation - Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source, or (b) human body fluids, cells, tissues, or organs that have had *ex vivo* contact with live, nonhuman animal cells, tissues, or organs.

Cadaveric organ donation grew 3 percent per year on average nationally from 1997 to 1999. During the same period, cadaveric donations for the Maryland and Washington regions increased 22 percent per year on average. This positive improvement in organ donation can be partly attributed to the William H. Amoss Organ and Tissue Donation Act, which was enacted by the Maryland General Assembly in April 1998.

Cadaveric Donors Procured by Selected OPOs: 1997-1999

	1997	1998	1999	Average Increase per Year (1997-1999)
TRC	52	68	78	25%
WRTC	65	67	91	20%
Total TRC/WRTC	**117**	**135**	**169**	**22%**
Total National	**5,477**	**5,801**	**5,849**	**3%**

Source: UNOS OPTN Data as of September 5, 2000.

Despite the encouraging increase in organ donations, the number of transplant procedures cannot meet the increasing number of people added to the waiting list for Maryland patients.

There are two major types of stem cell transplantation. They are categorized based on donor types: autologous and allogeneic. IBMTR/ABMTR reports the use of stem cell transplants to be increasing nationally for data available from 1975 to 1998.

Utilization of stem cell transplants in Maryland and Washington regions had been steadily increasing; however, autologous transplants had a 17 percent decrease from 1998 to 1999. This dramatic drop after steady growth is most likely due to disappointing preliminary results in several recent autologous trials in breast cancer. Although there was an average 15 percent increase per year from 1997 to 1999 for allogeneic transplants, there are indications that there is a leveling off of transplants mainly due to limited availability of HLA-matched donors, limited success to date with more disparate donors and a slower expansion into new diagnoses.

Utilization at Maryland & Washington Regional Transplant Centers for Stem Cell Transplantation: 1997-1999

Stem Cell Transplant	1997	1998	1999	Average Increase per Year (1997-1999)
Autologous	352	394	327	-3%
Allogeneic	114	144	148	15%
Total	**466**	**538**	**475**	**1%**

Sources: Maryland Discharge Abstract, DC Discharge Data, Fairfax Hospital.

Glossary of Terms

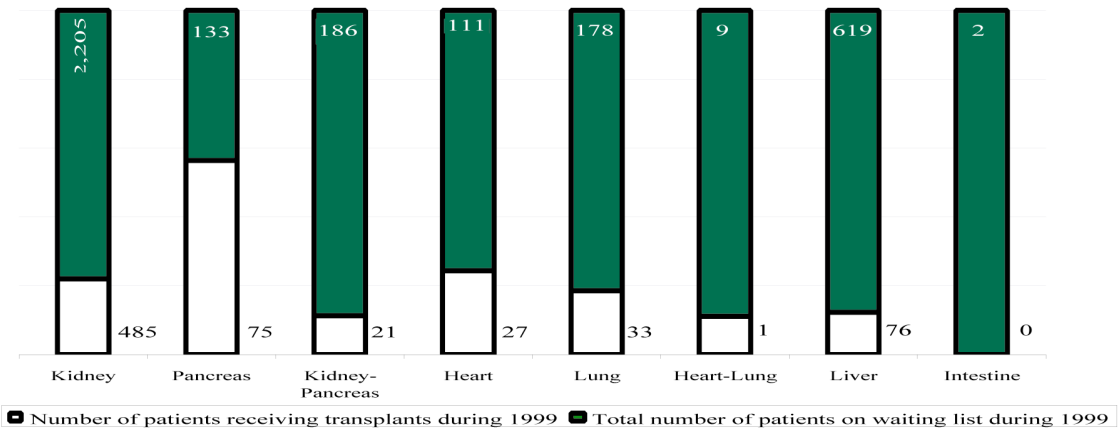
Allogeneic transplants - Blood or bone marrow cells transplanted from another person, usually a sibling but sometimes another relative or an unrelated donor.

Autologous transplants -The patient's own blood or bone marrow cells are removed prior to high-dose therapy, frozen and later transplanted back.

Human leukocyte antigens (HLA) - The antigens help the immune system to recognize whether or not a cell is foreign to the body. HLA are used to determine the compatibility of organs and cells for transplantation from one individual to another.

IBMTR/ABMTR - International Bone Marrow Transplant Registry and Autologous Blood & Marrow Transplant Registry - IBMTR collects and reports outcome data from blood and marrow transplant centers worldwide.

Patients on the Waiting List Compared to Those Receiving Transplants: Centers in the Maryland Region during 1999



Source: UNOS OPTN Data as of August 5, 2000 (waiting list), data as of July 13, 2001 (receiving transplant).

Sources of data and information

1. United Network for Organ Sharing. www.unos.org. Retrieved July 2001
2. IBMTR/ABMTR: Report on State of the Art in Blood and Marrow Transplantation – IBMTR/ABMTR Summary Slides with Guide, 2000.

MARYLAND HEALTH CARE COMMISSION Donald E. Wilson, M.D., MACP, Chairman
4201 Patterson Avenue, Baltimore, MD 21215, Tel: (410) 764-3460 Fax: (410) 358-1236 www.mhcc.state.md.us